K062533/A1

NEUROVIRTUAL
2315NW 107th Avenue - B.133 - WH. 1A16
Doral, FL - USA - 33172
Phone: (786) 693-8200 - Fax (305) 393-8429



Section 5
## 510(k) SUMMARY

DEC 22 2006

**A) Submitter's Name:** Neurovirtual USA, Inc.

**Owner / Operator Registration Number:** _____
**Manufacture Registration Number:** _____

**B) Address:** 2315NW 107th Ave - B.133 - WH. 1A16
Doral, FL - 33172

**C) Phone and Fax Numbers**
**Phone:** (786) 693-8200
**Fax:** (305) 393-8429

**D) Contact Person:** Eduardo J.M. Faria

**E) Preparation Date:** August 14, 2006
November 28, 2006 (Reviewed)

**F) Classification Name:**
**Common / Usual Name:** Electroencephalograph
**Proprietary Name:** BWII Digital (Amplifier and Power Module)
**Product Code:** GWQ
**Class:** Class II
**Regulation:** 882.1400

**Common / Usual Name:** Analyzer, spectrum, electroencephalogram signal
**Proprietary Name:** BWAnalysis (Software)
**Product Code:** OLT, GWQ, OLV
**Class:** Class II
**Regulation:** 882.1420



**G) Substantial Equivalence:**

The BWII Digital (Amplifier and Power Module) is equivalent with the following products:

| 510(k) Number | Model | Manufacture |
|---|---|---|
| K932407 | Easy Write and Easy Reader | Cadwell Laboratories, Inc. |
| K991900 | XLTEC PSG-40 Polysomnography | Excel Tech Ltd. |

K39

NEUROVIRTUAL
2315NW 107th Avenue - B.133 - WH. 1A16
Doral, FL - USA - 33172
Phone: (786) 693-8200 - Fax (305) 393-8429



And the BWAnalysis software is equivalent with the following:

| 510(k) Number | Model | Manufacture |
|---|---|---|
| K980214 | Excel Neuro Works | Excel Tech Ltd. |
| K932407 | Easy Write and Easy Reader | Cadwell Laboratories, Inc. |
| K974718 | Persyst Prism | Persyst Development Corp. |

**F) Description:**

BWII is multi-channel (up to 25 channels) system designed for electroencephalograph (EEG) and polysomnography (PSG) recording application, in sleep lab, hospital or clinical environment under the supervision of a physician, using a lap top or a desk top computer.

The BWII system consists of three major components: the Amplifier Unit, the Power Module (Both plastic made) and the BWAnalysis Software (a CD to be installed on a regular PC). The system provides connections for electrodes and sensors, and connects to the computer using an Ethernet cable.

The BWII works with any good quality patient leads / electrodes and sensors (snore, flow, effort belts and position) that have the safety touch connectors and are legally marketed in accordance with FDA requirements. As these accessories are already legally on the market from different manufactures, they are not part of this submission.

The BWII does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

**I) Intended Used:**

The BWII system may be used for electroencephalography (EEG) and sleep recordings (polysomnography) in research and clinical environments. It acquires, displays, and archives EEG and PSG data for on screen review, annotation and event marking by the user. The BWII system also allows for computer-assisted, user-controlled quantitative analysis of EEG.

The BWII system is not intended to replace conventional devices or methods used for EEG and PSG monitoring in critical care or intraoperative settings.

The BWII system requires competent user input, and its output must be reviewed and interpreted by a trained technicians or neurologists who will exercise professional judgment in using this information.

NEUROVIRTUAL
2315NW 107th Avenue - B.133 - WH. 1A16
Doral, FL - USA - 33172
Phone: (786) 693-8200 - Fax (305) 393-8429

The BWII system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

### J) Technological Characteristics:

| | Neurovirtual BWII | Cadwell Easy Write | Excel Tech PSG-40 | Excel Tech Neuro Works |
|---|---|---|---|---|
| **HARWARE** | | | | |
| **510(k) Number** | K062533 | K932407 | K991900 | K980214 |
| **Classification** | Electroencephalograph | Electroencephalograph | Electroencephalograph | Electroencephalograph |
| **Application** | EEG and PSG | EEG and PSG | EEG and PSG | EEG |
| **Number of Channels** | Up to 25 | 32 | 40 | 40 |
| **Data Communication** | Ethernet | Ethernet | Ethernet | Ethernet |
| **Material (External)** | Hard Plastic | Hard Plastic | Hard Plastic | Hard Plastic |
| **Power Source** | External Power Module | External Power Module | Internal Power Module | Internal Power Module |
| **SOFTWARE** | | | | |
| **Platform** | Windows XP | Windows XP | Windows XP | Windows NT |
| **Impedance** | YES | YES | YES | YES |
| **Calibration** | YES | YES | YES | YES |
| **Spectrum Analyzer (Frequency and Power)** | YES | YES | YES | YES |
| **Montage Editor** | YES | YES | YES | YES |

### K) Safety and Effectiveness:

The BWII is in compliance with the applicable clauses of the following standards:

- EN 60601-1:1990, "Medical Device Equipment: General Requirements for Safety"
- EN 60601-1-1:2000, Medical electrical equipment - Part 1: General requirements for safety - Section 1: Collateral standard: Safety requirements for medical electrical systems
- EN 60601-2: 2001, "Medical Device Equipment – General Requirements for Safety, Collateral Standard: Electromagnetic Compatibility, Requirements and Test"
- EN 60601-2-26:1994, "Medical Device Equipment – Particular requirements for the safety of electroencephalographs"
- EN 60601-1-4: 1996, "Medical Device Equipment – General Requirement for Safety, Collateral Standard: Programmable Electrical Medical Systems"
- EN ISO 14971:2000, "Medical Devices: Application of Risk Management to Medical Devices"

NEUROVIRTUAL
2315NW 107th Avenue - B.133 - WH. 1A16
Doral, FL - USA - 33172
Phone: (786) 693-8200 - Fax (305) 393-8429

- EN 13485: 2003, "Medical Devices, Quality Management Systems: Requirements for Regulatory Purposes"

- General Principles of Software Validation: FDA Guidance software validation version 1.1 (June 09, 1997)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neurovirtual
c/o Mr. Eduardo J.M. Faria
President
2315 NW 107th Avenue
Box #133 Warehouse 1A16
Doral, Florida 33172

APR - 9 2012

Re: K062533
Trade/Device Name: BWII Digital EEG and BWII Digital PSG with BWAnalysis Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, GWQ, OLV
Dated (Date on orig SE ltr): December 8, 2006
Received (Date on orig SE ltr): December 19, 2006

Dear Mr. Faria:

This letter corrects our substantially equivalent letter of January 16, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NEUROVIRTUAL

2315NW 107th Avenue - B.133 - WH. 1A16
Doral, FL - USA - 33172
Phone: (786) 693-8200 - Fax (305) 393-8429

Section 4

## Indications for Use

510(k) Number (if known): K062533

Device Name: BWII Digital EEG and BWII Digital PSG with BWAnalysis Software

Indications for Use:

The BWII system may be used for electroencephalography (EEG) and sleep recordings (polysomnography) in research and clinical environments. It acquires, displays, and archives EEG and PSG data for on screen review, annotation and event marking by the user. The BWII system also allows for computer-assisted, user-controlled quantitative analysis of EEG.

The BWII system is not intended to replace conventional devices or methods used for EEG and PSG monitoring in critical care or intraoperative settings.

The BWII system requires competent user input, and its output must be reviewed and interpreted by a trained technicians or neurologists who will exercise professional judgment in using this information.

The BWII system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062533